UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 17 2017

[redacted]

[redacted]

Re: Prenotice Communication 7693

Dear [redacted]

You wrote to Dave Schutz of my staff and described [redacted] interest in making and providing isotope [redacted] to a customer which intends to make [redacted]-containing scintillation crystals for use in radiation detection. [redacted] has been purchasing [redacted] for R&D use compliant with 40 CFR 720.36 and .78. The purchased [redacted] had been enriched relative to the [redacted] natural isotopic abundance by the [redacted], which had prepared it before the passage of the Toxic Substances Control Act and which had not filed any Section 5 notice on the material during the time since TSCA was passed.

You have described the situation as follows: your customer intends to use the purchased [redacted] as an intermediate in manufacture of scintillation crystals for detection of radiation. As you are aware, any new chemical substance which will be manufactured or imported in small quantities solely for research and development (R&D) in accordance with procedural and recordkeeping requirements at 40 CFR Sections 720.36 and 720.78 is exempt from premanufacture notice (PMN) requirements and from Inventory listing. For this exemption to apply, the chemical substance must either be the focus of R&D itself, or be used in R&D activity focusing on another substance, and this includes health or environmental effects testing. You raised three issues in your letter. For clarity, I will identify those questions in this text, then answer them. Overall, the letter will suggest that use of the R&D exemption can be lawful for [redacted] if the use is very limited, but is not the only, and is likely not to be the optimal, course of action for the company. The first question you have raised in your letter is whether this

exemption can be applied to reagents and chemical substances used in manufacture of a radiation detector. Second, if [redacted] provides a [redacted] salt it has pelletized to the customer, which then makes the scintillation crystal, can that manufacture be considered to be for exempt R&D? Third, if the R&D exemption is not relied on, what mechanism can bring the non-Inventory-listed [redacted] materials from your supplier into compliance with TSCA section 5 for distribution in commerce?

In answer to your first question, in discussing the exemption it's been our position that if something like this radiation detector is for use outside of an R&D setting, then as in the case of a generally available test kit, the chemicals used to make it would be reportable – guidance we have provided is: "The substance must either be the focus of R&D itself, or be used in an R&D activity focusing on another chemical substance. The latter category encompasses reagents, chemicals to be used as standards for chemical analysis in laboratories, and intermediates used solely to produce R&D substances, including intermediates used in the production of pesticides used exclusively for R&D..... R&D encompasses a wide range of activities which may occur in a laboratory, pilot plant, commercial plant outside the research facility, or at other sites appropriate for R&D. The following activities which test the physical, chemical, production, and performance characteristics of a substance may be considered as R&D.... Health and environmental effects testing."

This suggests that, if use of your customer's scintillation counters were limited to a specific program of testing the effects of a particular chemical substance's release into the environment or in relation to some health effect of the substance, the function of the scintillation crystals could be considered to be health or environmental testing of the substance, and in that case the use of the crystals could be included in the exemption if all procedural and recordkeeping provisions of the R&D exemption at 40 CFR Sections 720.36 and 720.78 are maintained. This includes the provision requiring the review and evaluation of risk information associated with the R&D substance as required at 40 CFR Section 720.36(b)(1) and that at Section 720.36(c)(2) to notify customers in writing that the substance is to be used only for R&D purposes and to provide the notice of any health risk associated with the substance. The impression created by your question, however, is that the scintillation counters which your customer intends are for general radiation testing and not limited to a specific program of research. We expect that it will be somewhat demanding to maintain the procedural and record-keeping requirements of exempt R&D for scintillation crystals in test machinery, and that to ensure that they were only used in an R&D setting would likely limit their value substantially.

For your second question, if the pelletized salt is an intermediate chemical substance made solely for use consistent with exempt R&D after further synthesis, that intermediate material can be made under the R&D exemption, as well.

Your third question, then, is [redacted] best strategy to get the non-listed [redacted] materials from your supplier into compliance with Inventory requirements - as they must be if they are to be used in radiation detectors which are not made and tracked in compliance with the R&D exemption.

We do receive and review Section 5 submissions from other agencies of the government. The facts here as you have described them are unusual: the [redacted] was enriched before TSCA was passed and has been stockpiled at [redacted] since. It was not notified for the Initial TSCA Inventory, and if it was not then intended for commercial use was not necessary at that time. [redacted] made it available to you for R&D use, which did not trigger an Inventory listing requirement. Your or [redacted] situation is unusual here, but because the [redacted] was enriched before TSCA went into effect and if there was at the time of the Initial TSCA Inventory no commercial intent for the material, it is now appropriate to consider it as surplus R&D material: excess R&D material remaining after the R&D has been completed can be used for commercial activities other than compliant R&D, but only after a section 5 notice has been successfully submitted by its maker (in this case, [redacted] for the [redacted] and the [redacted] for the [redacted]) and EPA has made a determination. That's the course of action we suggest. If you wish further response to your concerns, please contact Dave Schutz of my staff on 202 564 9262.

Sincerely,

Greg Schweer, Chief
New Chemicals Notice Management Branch
Chemical Control Division (7405M)